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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,633	04/20/2001	Gregory A. Demopulos	OMER117356	2163

26389 7590 07/13/2004

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/839,633	<b>Applicant(s)</b> DEMOPULOS ET AL.	
	<b>Examiner</b> Eileen O'Hara	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 22, 25-39, 41 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 25-39, 41 and 44-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 20, 22, 25-39, 41 and 44-50 are pending in the instant application. Claims 20, 22, 39, 49 and 50 have been amended as requested by Applicant in the Paper filed April 21, 2004.

#### *Withdrawn Objections and Rejections*

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

#### *Claim Objections*

3. Claim 3 is objected to because of the following informalities: "*The* isolated nucleic acid molecule" on the first line should be "*An* isolated nucleic acid molecule". Appropriate correction is required.

#### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 20, 22 and 25-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,820,583, claims 1-27 of U.S. Patent No. 6,056,715, claims 1-34 of U.S. Patent No. 6,210,394, claims 1-34 of U.S. Patent No. 6,210,394, claims 1-23 of U.S. Patent No. 6,413,961, claims 1-32 of U.S. Patent No. 6,254,585, claims 1-31 of U.S. Patent No. 6,420,432, claims 1-26 of U.S. Patent No. 6,492,332, claims 1-36 of U.S. Patent No. 6,645,168. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant application is drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising at least one tumor necrosis factor soluble receptor, applied locally and perioperatively to the surgical site, and the claims of the other patents are drawn to methods of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising a number of anti-inflammatory or pain reducing compounds. It would be *prima facie* obvious to one of ordinary skill in the art to administer an antagonist to a inflammatory cytokine before, during and after a surgical procedure as in the methods of the patents, since it was known that TNF is produced in response to a surgical wound.

Claims 20, 22, 25-39, 41 and 44-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/180,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant application is drawn to a method of preemptively inhibiting pain and inflammation at a wound during a

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surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising at least one tumor necrosis factor soluble receptor, applied locally and perioperatively to the surgical site, and the claims of the other patents are drawn to methods of inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising a number of anti-inflammatory or pain reducing compounds. It would be *prima facie* obvious to one of ordinary skill in the art to administer an antagonist to a inflammatory cytokine before, during and after a surgical procedure as in the methods of the applications, since it was known that TNF is produced in response to a surgical wound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20, 22, 25-39, 41 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 20, 22, 25-39, 41 and 44-50 encompass a solution and method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a

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surgical procedure a solution comprising at least one tumor necrosis factor soluble receptor. One of the activities of tumor necrosis factor is producing inflammation. However, there is no disclosure or evidence in the instant application or in the prior art that TNF produces pain. Therefore, a solution comprising at least one TNF soluble receptor would not inhibit pain, and the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29 and 44 are indefinite because they encompass a solution and method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising at least one tumor necrosis factor soluble receptor, applied locally and perioperatively to the surgical site, wherein the solution is locally applied to the wound in the absence of “metabolic transformation”, and although the specification discusses metabolic transformation, there is no definition of what this term means.

#### ***Priority Determination***

7. The effective priority date of the instant application for solutions comprising sTNFR or rhTNFR:Fc is the filing date of the instant application, April 20, 2001, since none of the parent applications disclosed such solutions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8.1 Claims 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., U.S. Patent No. 5,945,397. Claims 39 and 41 encompass solutions comprising at least one tumor necrosis factor soluble receptor. Smith et al. teach solutions comprising soluble TNF receptors, wherein the solutions comprise carriers (column 4, lines 20-30), and pharmaceutical compositions and methods of therapeutic treatment (column 15, line 52 to column 16, line 29, claims). Therefore, Smith et al. anticipates the claims.

8.2 Claims 39, 41 and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai., U.S. Patent No. 5,747,532. Claims 39, 41 and 44-50 encompass solutions comprising at least one tumor necrosis factor soluble receptor and at least one additional pain/inflammation inhibitory agent that may be an interleukin receptor antagonist. Lai teaches pharmaceutical compositions comprising at least soluble TNF receptors and IL-1 receptor antagonists (see claim 22). Therefore, Lai anticipates the claims.

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***Conclusion***

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, se <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

A handwritten signature in black ink that reads "Eileen B. O'Hara". The signature is written in a cursive, flowing style.

Patent Examiner